IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS PHARMACEUTICALS CORPORATION, NOVARTIS AG, NOVARTIS PHARMA AG, NOVARTIS INTERNATIONAL PHARMACEUTICAL LTD. and LTS LOHMANN THERAPIE-SYSTEME AG Plaintiffs, v. PAR PHARMACEUTICAL, INC. Defendant.	C.A. No. 11-1077-RGA C.A. No. 13-1467-RGA REDACTED PUBLIC VERSION

PAR PHARMACEUTICAL, INC.'S
RESPONSIVE POST-TRIAL BRIEF ON NON-INFRINGEMENT

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Par	Defendant Par Pharmaceutical, Inc.
Plaintiffs	Plaintiffs Novartis Pharmaceuticals Corporation, Novartis AG, Novartis Pharma AG, Novartis International Pharmaceutical Ltd., and LTS Lohmann Therapie-Systeme AG
Novartis	Plaintiffs Novartis Pharmaceuticals Corporation, Novartis AG, Novartis Pharma AG, Novartis International Pharmaceutical Ltd.
LTS	Plaintiff LTS Lohmann Therapie-Systeme AG
'031 patent	U.S. Patent No. 6,335,031
ANDA	Abbreviated New Drug Application
FDA	Food and Drug Administration
PTX	Plaintiffs' admitted trial exhibit
DTX	Defendant's admitted trial exhibit
JTX	Joint admitted trial exhibit
Tr. __:__	The corresponding page and line of the trial transcript, May 1-2, 2014 (D.I. 398, 399)

Note: All emphases added throughout unless otherwise indicated.

I. INTRODUCTION

Only a single infringement issue remains in this case: whether Plaintiffs proved by a preponderance of the evidence that Par's ANDA rivastigmine patch contains "about 0.01 to about 0.5 percent by weight of an antioxidant." Plaintiffs failed to meet their burden. Par's ANDA product contains no antioxidant, much less one in the claimed range.

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Because of the high purity of the polymer adhesive, no antioxidant is necessary, and Par's ANDA states that no antioxidant is used.

Indeed, for many months after Plaintiffs received Par's ANDA, Plaintiffs were unable to identify any antioxidant in Par's product. DTX 568 at 11. Plaintiffs' infringement theory surfaced only when their expert Dr. Davies—months after obtaining copious amounts of every component of Par's ANDA product—generated an eleventh-hour, litigation-specific experiment that he claimed showed infringement. Specifically, Dr. Davies asserted that his experiment showed that acetaldehyde—a minute impurity measured in some batches of the rollstock for Par's ANDA product—was an antioxidant. But Dr. Davies' idiosyncratic, litigation-induced experiment wholly failed to establish that acetaldehyde is an antioxidant. First, the experiment fails to meet the *Daubert* standard because it has never been used outside of this litigation, is not peer-reviewed, lacks adequate controls, and fails to show statistically significant results. The experiment should therefore not be considered, and if considered it is entitled to little or no weight. Second, Dr. Davies' experiment fails to provide evidence that acetaldehyde is an antioxidant under the Court's claim construction. This Court construed "antioxidant" to mean "agent that reduces oxidative degradation." As Plaintiffs' expert Dr. Klibanov has agreed, this construction means that the compound in question has a "generalized" ability to reduce oxidative

degradation. The antioxidants listed in the '031 patent are all well-known antioxidants for which extensive published literature exists, and a person of ordinary skill can thus have the expectation that in a variety of circumstances, each will function as an agent that reduces oxidative degradation. Dr. Davies' single experiment, performed under extreme, non-standard conditions, does not show that acetaldehyde has a generalized ability to do anything.

Par produced compelling evidence that acetaldehyde is not an antioxidant. Acetaldehyde has never been referred to in the pharmaceutical literature as an antioxidant, and in fact has never been used as a pharmaceutical excipient for any purpose. It appears in Par's ANDA product only as a manufacturing impurity. Par's FDA stability testing on batches with no acetaldehyde and batches with acetaldehyde, show that acetaldehyde does not reduce oxidative degradation. Par's FDA stability testing is the ***only*** testing in this case done under conditions specified in the '031 patent for evaluating antioxidant behavior.

Further, Plaintiffs' only asserted evidence to show that Par's ANDA product meets the range limitation "about 0.01 to about 0.5 percent by weight of an antioxidant" is Dr. Davies' testimony that Par's ANDA specification permits up to 1000 ppm (0.1%) acetaldehyde in the rollstock. Plaintiffs assert that under *Sunovion*, the Court need not consider the product that will likely be sold following approval. Plaintiffs are incorrect. *Sunovion* did not change the established law that infringement in an ANDA case is determined by what the ANDA applicant will likely sell if the ANDA is approved. The measured levels of acetaldehyde in batches of Par's ANDA products (from none detected up to 0.003%) fall below the claimed range.

II. PAR DOES NOT INFRINGE CLAIM 7 OF THE '031 PATENT

A. Legal Standards

A determination of infringement requires that the claim be properly construed, and the properly construed claim must then be compared to the accused product. *Liquid Dynamics Corp.*

v. Vaughan Co., 355 F.3d 1361, 1367 (Fed. Cir. 2004). The patentee must show infringement by a preponderance of the evidence. *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1570 (Fed. Cir. 1997).

The ANDA infringement inquiry focuses on "a comparison of the asserted patent against the product that is likely to be sold following ANDA approval." *Alcon Research Ltd. v. Barr Labs., Inc.*, 745 F.3d 1180, 1186 (Fed. Cir. 2014) (citation omitted); *Glaxo*, 110 F.3d at 1568-70 ("What is likely to be sold, or, preferably, what will be sold, will ultimately determine whether infringement exists."). The determination of the product likely to be sold following ANDA approval "is based on consideration of all of the relevant evidence and, because drug manufacturers are bound by strict statutory provisions to sell only those products that comport with the ANDA's description of the drug, an ANDA specification defining a proposed generic drug in a manner that directly addresses the issue of infringement will control the infringement inquiry." *Alcon*, 745 F.3d at 1186 (citing *Sunovion Pharm., Inc. v. Teva Pharm. USA, Inc.*, 731 F.3d 1271, 1279-80 (Fed. Cir. 2013), and *Glaxo*, 110 F.3d at 1569-70.)

B. The Court's Claim Construction

Asserted Claim 7 of the '031 patent is directed to a transdermal device comprising a pharmaceutical composition, and requires "about 0.01 to about 0.5 percent by weight of an antioxidant." JTX 001 at 8:49-51. The Court construed "antioxidant" to mean "agent that reduces oxidative degradation." D.I. 250. Antioxidants are a class of compounds that are known in the art. *See* Tr. 438:1-439:8 (Buckton); DTX 505 at 857; JTX 106 at 203. Consistent with the Court's construction, antioxidants have a ***generalized*** ability to reduce oxidative degradation, even though they may not work in every instance. *See* Tr. 602:23-603:6; 603:15-23 (Klibanov).

Plaintiffs assert that Par's experts "ignore[d] the Court's claim construction" during trial. D.I. 403 at 17-18. But Plaintiffs confuse claim construction with the evidence necessary to prove

infringement. Plaintiffs agree that under the Court's construction of "antioxidant," an antioxidant has a generalized ability to reduce oxidative degradation. D.I. 137-1 in Case No. 13-00052-RGA (D. Del.) ¶ 37.

Dr. Buckton applied the Court's claim construction in his analysis (Tr. 423:3-5), and explained why acetaldehyde is not an antioxidant described in the '031 patent. Tr. 436:8-22. Plaintiffs erroneously equate Dr. Buckton's discussion of what is described in the patent with a claim construction argument. But whether a particular compound is described in the patent is a separate issue from claim construction. *Trading Techs. Int'l, Inc. v. Open E Cry, LLC*, 728 F.3d 1309, 1319 (Fed. Cir. 2013) ("Despite their similarities, however, claim construction and the written description requirement are separate issues that serve distinct purposes.")

Plaintiffs sought—and successfully obtained—the construction of "antioxidant" by arguing that all that needs to be shown, for purposes of infringement, is that the antioxidant is present, and not that it is functioning in the composition. *See, e.g.*, D.I. 244 at 8:3-16; *see also* D.I. 149 in Case No. 13-00052-RGA at 6:8-11. Plaintiffs' counsel agreed with the Court that the term "antioxidant" is a term that is "well understood by a person of ordinary skill in the art." D.I. 244 at 5:24-6:11. But nothing in the Court's claim construction specified the quantum of proof necessary to establish that a compound is an "agent that reduces oxidative degradation."

C. Par's ANDA Products Do Not Contain an Antioxidant

Par's ANDA rivastigmine transdermal products do not contain an antioxidant. The drug-in-adhesive layer of Par's ANDA products contains the active ingredient rivastigmine, the acetate copolymer adhesive R-27149, and a tackifier, isopropyl myristate. Tr. 430:8-432:1. Par's ANDA compares the inactive ingredients in the ANDA product with the Exelon® patch, and states that Par's ANDA product has no antioxidant ("n/a" or not applicable), while Exelon® has Vitamin E (tocopherol) as an antioxidant. Tr. 432:2-23 (Buckton); DTX 595 at 231-233.

Par's ANDA products use an adhesive that was specifically developed to avoid the use of an antioxidant.

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Dr. Buckton testified that Par's ANDA products do not contain an antioxidant. Tr. 421:10-422:1; 436:1-3.

D. Plaintiffs Failed to Show that Acetaldehyde Is an Antioxidant

Plaintiffs make two arguments to try to show that acetaldehyde is an antioxidant: (1) acetaldehyde is described in the literature as a "reducing agent," and (2) the single test by Dr.

[1] 3M filed a patent application for its novel manufacturing process that reduces impurities, such as acetaldehyde. Tr. 302:13-304:6 (Dizio); JTX 017.

Davies purportedly showed that acetaldehyde reduced oxidative degradation of rivastigmine. D.I. 403 at 3. But Plaintiffs' evidence is wholly insufficient to establish that acetaldehyde is an antioxidant. First, Plaintiffs' "reducing agent" argument fails to withstand cursory scrutiny. Although many compounds can act as reducing agents, this does not mean they are antioxidants. Tr. 238:22-239:4 (Ganem). And Dr. Davies' experiment—which he designed and conducted at the eleventh hour before expert reports were due—is unreliable and should not be considered.

1. Acetaldehyde Does Not Reduce Oxidative Degradation, but Rather Promotes Oxidation

Acetaldehyde is not an antioxidant because it does not suppress the cycle of oxidative degradation. As Dr. Ganem testified, "oxidative degradation is the process by which the oxidation level of [a] chemical compound results in the decomposition." Tr. 232:17-233:16. Dr. Ganem explained the "core cycle of oxidative degradation," which is a chain reaction and "can propagate itself many, many times, going around and around this cycle driving the transformation of an organic compound to the oxidative degradation products." Tr. 233:21-234:235:1. The antioxidants listed in the '031 patent are all "well-known antioxidants for which extensive published literature exists," and "have the unique ability to shut down or suppress this cycle of oxidative degradation" in several ways. Tr. 235:17-237:5 (Ganem); 170:7-172:21; JTX 001 at 4:10-19; DTX 526.

In contrast to the listed antioxidants, acetaldehyde does not form a stable radical and cannot break the cycle of oxidative degradation. Acetaldehyde "can form a radical, but it's a highly reactive radical that can itself contribute to oxidative degradation." Tr. 237:6-16 (Ganem). The mechanisms by which acetaldehyde can form a reactive peroxide are "well worked out in the chemical literature." Tr. 239:16-240:1 (Ganem). As described in *Chemical Reviews*, the principal review journal of the American Chemical Society, acetaldehyde

undergoes oxidation to form four different chemical radicals, "[a]ll of which are reactive enough to contribute to oxidative degradation." Tr. 240:2-242:2 (Ganem); JTX 86 at 345. Based on these chemical reactions, Dr. Ganem testified that "chemist[s] consider acetaldehyde an extremely reactive radical." Tr. 242:3-13; 237:24-238:6.

The chemical radicals and peracids in the McNesby article (JTX 86) are described as "stable" at extremely low temperatures, and from that premise Plaintiffs incorrectly argue that those radicals would not be formed at room temperature. D.I. 403 at 16. Plaintiffs are simply wrong. McNesby reported that certain researchers had been able to ***isolate a complex*** that included the peroxide and was stable at -30° C. JTX 86 at 328. As Dr. Ganem explained, this low-temperature work was done to understand the reactive pathways by which reactive (i.e. unstable) radicals are formed. All of the processes by which acetaldehyde forms reactive radicals "can occur readily at room temperature." Tr. 242:14-243:1. Therefore, acetaldehyde enhances—rather than suppresses—oxidative degradation.

2. Acetaldehyde Is a Reducing Agent but Not an Antioxidant

Plaintiffs assert that because acetaldehyde is a reducing agent, and because some antioxidants function by acting as reducing agents, acetaldehyde can function as an antioxidant. D.I. 403 at 3. This argument is a straightforward logical fallacy. "Lot[s] of compounds can be reducing agents, but that does not mean that they can disrupt this engine, this cycle of oxidative degradation." Tr. 238:22-239:4 (Ganem). None of Plaintiffs' experts testified that all, most, or even any appreciable number of reducing agents are antioxidants. A reducing agent is a substance that "will reduce some other chemical substance and, in turn, become oxidized." Tr. 238:17-21 (Ganem). But the mere fact that acetaldehyde can be oxidized does not qualify it as an antioxidant, because as discussed above, it forms a reactive free radical and in turn enhances oxidative degradation. Tr. 239:5-14, 243:2-20 (Ganem). This is in contrast to well-known

antioxidants such as ascorbyl palmitate and ascorbic acid, that act as reducing agents ***and*** break the cycle of oxidative degradation. *See* Tr. 235:17-237:5 (Ganem). Indeed, Dr. Davies did not even consider whether acetaldehyde was a known oxidizing agent when forming his opinion that acetaldehyde was an antioxidant. Tr. 164:21-165:2. Therefore, the fact that acetaldehyde may act as a reducing agent in some instances provides no evidence that it is an antioxidant.

3. Acetaldehyde Is Not Recognized As an Antioxidant

Acetaldehyde is not recognized as an antioxidant. Tr. 436:6-22, 439:12-440:8 (Buckton). Dr. Buckton, an expert on drug substance testing, formulation development and stability testing of pharmaceutical products (Tr. 418:22-419:1), testified that acetaldehyde has never been used as an antioxidant, as evidenced by the FDA inactive ingredient list, and that in "all my years of experience was such that, you know, my work as a formulation that I hadn't seen it used."[2] Tr. 436:6-22, 439:12-440:8; 503:5-7. Dr. Ganem further testified that in his 40 years as a chemistry professor with expertise in oxidation and reduction reactions (Tr. 231:2-9, 232:9-15), he had never heard of acetaldehyde reported as an antioxidant, and that "chemists do not consider it to be an antioxidant." Tr. 238:7-14. Dr. Klibanov, an expert in chemistry and pharmaceutical formulations, including the use of antioxidants and oxidative degradation (Tr. 553:9-13)—who testified in the Watson trial that BHT was an antioxidant—provided no opinions during this litigation that acetaldehyde was an antioxidant, in response to Dr. Ganem.[3]

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[2] Plaintiffs assert that a Chinese patent not admitted into evidence shows that acetaldehyde is an antioxidant, based solely on citation to counsel's cross-examination questions and characterization of the document. D.I. 403 at 19. That is not proper evidence. *Galen Med. Assocs. Inc. v. United States*, 369 F.3d 1324, 1338-39 (Fed. Cir. 2004) ("Statements of counsel [in briefing and oral argument], however, are not evidence.").

[3] Par respectfully requests that the Court confirm that it has granted Par's motion to strike Dr. Klibanov's testimony at 597:1-598:6 as not previously offered in Dr. Klibanov's expert reports, because Plaintiffs did not produce a copy of the expert report with that testimony in their post-trial brief. Tr. 598:13-601:12.

Moreover, acetaldehyde is not identified in the pharmaceutical literature as an antioxidant. Tr. 439:6-8 (Buckton). For example, the *Handbook of Pharmaceutical Excipients*, a comprehensive listing of excipients used in pharmaceutical products (Tr. 417:20-24), lists antioxidants but does not include acetaldehyde. Tr. 438:16-439:5 (Buckton); DTX 505 at 857; *see also* JTX 106 at 203. Dr. Davies also admitted that acetaldehyde is not identified as an antioxidant in the pharmaceutical literature. Tr. 81:6-8 (acetaldehyde is not listed in the FDA inactive ingredients list); *see also* 160:10-20, 161:5-9; JTX 061; JTX 063 (*Van Nostrand's Concise Encyclopedia of Science* and the *Specialty Chemicals Source Book* do not identify acetaldehyde as an antioxidant). Further, the '031 patent does not identify acetaldehyde as an antioxidant. Tr. 237:20-23 (Ganem); 436:23-437:13 (Buckton). The '031 patent lists well-known, established pharmaceutical antioxidants as having an "effective stabilizing effect." Tr. 437:13-19 (Buckton); 235:17-236:2 (Ganem). Therefore, a person of ordinary skill in the art reading the '031 patent would not understand that acetaldehyde was an antioxidant.

4. Par's Testing Shows that Acetaldehyde Is Not an Antioxidant

Par conducted the proper stability tests described in the '031 patent for evaluating antioxidant behavior, which demonstrate that acetaldehyde is not an antioxidant. It is undisputed that accelerated stability tests on a finished pharmaceutical formulation, as disclosed in the '031 patent, are a proper method to evaluate antioxidant behavior. JTX 001 at 4:20-30; Tr. 175:23-176:14 (Davies); 440:9-443:14 (Buckton); 592:4-12 (Klibanov). Dr. Buckton testified that it was standard to take a formulation with and without the proposed antioxidant, and conduct accelerated stability testing to determine whether the compound is an antioxidant. Tr. 445:17-446:20. This was confirmed by the '031 patent and the EMEA Guidance on Inclusion of Antioxidants. *Id.*; 443:15-445:16; JTX 105 at 2 ("The efficacy of antioxidants must be assessed in the finished product in conditions which simulate actual use by measuring the extent of

degradation in the finished product with and without the antioxidant.").

Stability tests on numerous batches of Par's ANDA product, at three different conditions, unanimously confirmed that acetaldehyde does not reduce oxidative degradation. Two batches of Par's ANDA product, lots 110110, and 110111, were made from rollstock that had no detectable acetaldehyde. Six batches of Par's ANDA product, lots 110280, 110281, 110319, 110320, 130108, and 130141, were made from rollstock that had measured levels of acetaldehyde from 8 to 30 ppm. Tr. 446:21-449:4 (Buckton); DTX 585B. Stability testing at 25° C/60% RH showed that the batches with no detectable acetaldehyde were entirely stable through the entire two-year shelf life, and showed "absolutely no evidence at all that acetaldehyde can reduce oxidative degradation because the product is clearly stable without any need for it." Tr. 449:19-451:21 (Buckton); DTX-588B. Data from the 30° C/65% RH accelerated condition further showed "no evidence whatsoever that acetaldehyde is reducing any degradation." Tr. 451:22-452:24 (Buckton); DTX-587B. And data from the 40° C/75% RH accelerated conditions (which are identified in the '031 patent as an appropriate test) also provided "no evidence of acetaldehyde protecting against oxidative degradation." Tr. 453:1-454:3 (Buckton); DTX 586B.

Plaintiffs try desperately to make lemonade out of the "lemon" fact that Par's FDA stability testing, using conditions specified in the '031 patent, shows that Par does not infringe. Plaintiffs incredibly argue that Par's testing is unreliable because it was ***not done*** for litigation purposes, but instead follows standard FDA requirements. D.I. 403 at 21-23. Plaintiffs' reasoning is incorrect—the standardized nature of the testing, and the fact that it is accepted by an independent governmental agency enhance its credibility, not the other way around.

First, Plaintiffs assert that Par's stability tests were not set up to determine whether acetaldehyde is an antioxidant. *Id.* at 21. But Dr. Buckton testified that the experimental design

of batches of a pharmaceutical formulation with and without acetaldehyde allowed him to draw that conclusion. Tr. 458:2-24. Second, Plaintiffs assert that Par's stability testing "lacked sufficient controls" because they were made from different lots of ingredients. D.I. 403 at 21. But the fact that Par's ANDA batches were made from different lots increases their reliability—FDA ***requires*** that the batches be made from different lots to demonstrate that the results are reproducible and robust. Tr. 459:1-21 (Buckton). Par's stability data "is internally consistent so it's a coherent data set all of which demonstrate stability and all of which can be relied upon to support the same overall view" that acetaldehyde is not an antioxidant. *Id.* Third, Plaintiffs assert that Par's stability testing is unreliable because Par "tests *one patch*" at a given time point. D.I. 403 at 22 (emphasis in original). But Plaintiffs fail to acknowledge that this testing meets FDA's rigorous requirements because numerous patches are tested for each batch throughout the duration of each condition. *See* DTX 588B (reflecting testing on 114 different patches); DTX 587B (reflecting testing on 100 different patches); DTX 586B (reflecting testing on 90 different patches). Dr. Buckton testified that you would "take the data set as a whole" (Tr. 524:10-525:18), that the data are "internally consistent" (Tr. 459:17-21), and that the data are reliable because they were "generated by validated methods and submitted to the FDA" (Tr. 457:5-18).

Next, Plaintiffs attempt to affirmatively rely on the fact that Par/3M developed a product that is stable without an antioxidant, asserting that Par's stability studies "failed to display sufficient oxidative degradation to demonstrate one way or another that acetaldehyde reduces the oxidative degradation of rivastigmine." D.I. 403 at 22-23. But Dr. Buckton testified specifically about the data from the six-month time point for the 40° C/75% RH condition, that "this column here will start to show some measurable numbers for degradation," but that he saw "no evidence of acetaldehyde protecting against oxidative degradation," and that the data across all conditions

was sufficient to allow him to draw the conclusion that acetaldehyde is not an antioxidant. Tr. 453:1-454:3; 457:19-458:1; DTX 586B.

Finally, Plaintiffs assert that Par should have conducted statistical analysis on its stability data. D.I. 403 at 23. But Dr. Buckton and Dr. Michniak both consistently testified that because the data showed no decrease in degradation corresponding to acetaldehyde concentration, statistical analysis on the data would not be meaningful. Tr. 526:3-527:15; 404:4-18. Since degradation in batches without acetaldehyde were not even numerically greater than batches with acetaldehyde, it is simply impossible for the data to show a statistically significant difference. Plaintiffs' laundry list of criticisms are thus unfounded.

5. Dr. Davies' Non-Standard Adaptation of a Forced Degradation Study Is Not Relevant

Plaintiffs urge the Court to disregard Par's FDA stability testing, and instead rely on Dr. Davies' testing designed specifically for this litigation, arguing that Par "fail[ed] to conduct testing relevant in weighing the evidence of infringement." D.I. 403 at 17. But as shown above, Par ***did*** conduct testing, and was the only party at trial to rely on stability testing disclosed in the '031 patent, which demonstrated that acetaldehyde is not an antioxidant.

It is Dr. Davies' litigation-induced test results that are unreliable. First, the circumstances surrounding his experiment demonstrate that Dr. Davies is a seasoned advocate, and that his test is anything but an objective effort to determine the properties of acetaldehyde. Tr. 176:15-194:5. Rather, the facts support the inference that Dr. Davies designed the experiment to obtain the results he wanted. Dr. Davies requested and obtained large quantities of every single component of Par's ANDA product, representing that these were "necessary and reasonable" for the testing he wanted to conduct. Tr. 182:1-22; DTX 112. Yet after receiving these materials, he waited nearly three months, with no explanation, before he designed and conducted his single

experiment—using essentially none of the materials he said were "necessary and reasonable." Plaintiffs represented in interrogatory responses that they were "in ***the process of testing*** Actavis' [Par's] ANDA Products" two-and-a-half months before Dr. Davies' experiment began, and expected such testing to take two to two-and-a-half months. Plaintiffs never produced those tests in the litigation. DTX 568 at 11 ("Plaintiffs are in the process of testing Actavis' [Par's] ANDA products to identify and quantify the antioxidant(s), expect such testing to be complete in two to two-and-one-half months"); *see also* JTX 33; DTX 111; DTX 112; DTX 113; DTX 114; DTX 120; JTX 170; D.I. 77 at 13-14. Though the Par materials were shipped directly to Dr. Davies and never left his facility, he purported to know nothing about the non-produced testing of those materials as described in Plaintiffs' interrogatory response. Tr. 191:16-23. Dr. Davies also protested that he could not make Par's ANDA product, and tried to excuse the extreme conditions of his experiment by asserting a purported lack of time. Of course, he provided no credible explanation for why after requesting large quantities of every ingredient needed to reproduce the Par product, he waited months until just before expert reports were due, to start his experiment. Tr. 191:24-194:5.

The evidence suggests that Dr. Davies' experiment was cherry-picked and litigation-driven. It is not reliable evidence of infringement. Dr. Davies' experiment should not be admitted, or be given only minimal weight. At best, Dr. Davies' test is a single result in an isolated test, using conditions irrelevant to any pharmaceutical product, and is insufficient evidence to establish that acetaldehyde is an agent that reduces oxidative degradation.

a. Dr. Davies' Experiment Is Not Reliable and Should Be Given Minimal or No Weight

Dr. Davies' experiment and related testimony should be excluded under Federal Rule of

Evidence 702[4], or given only minimal weight, for the same reasons that his study does not meet the Third Circuit's *Mitchell* factors for reliability under *Daubert*. *United States v. Mitchell*, 365 F.3d 215, 235 (3d Cir. 2004).

First, Dr. Davies' study does not consist of a testable hypothesis. The first *Mitchell* factor asks whether the proposition at issue is "capable of being proved false." *Warner Chilcott Labs. Ir. Ltd. v. Impax Labs., Inc.*, No. 2:08-cv-6304-WJM, 2012 WL 1551709, at *24 (D.N.J. Apr. 30, 2012) (citing *Mitchell*, 365 F.3d at 235), *aff'd*, 478 F. App'x 672 (Fed. Cir. 2012). Under Plaintiffs' theories, the results from a single study are sufficient to show that a compound is an antioxidant, but would not be sufficient to demonstrate that it is ***not*** an antioxidant. *See* D.I. 401, Section II.A.3.a. Because Dr. Davies' experiment cannot show that a compound is not an antioxidant, there is no testable hypothesis.

Second, Dr. Davies' experiment has not been subjected to peer-review. Tr. 480:6-8 (Buckton). There are no non-judicial uses of his experiment. These weigh in favor of exclusion. *Warner Chilcott*, 2012 WL 1551709, at *25-26. Dr. Davies conducted a non-standard adaptation of a forced degradation study, which has never been used before outside of the present litigation. Tr. 467:3-14 (Buckton) ("I haven't seen that kind of study before."); D.I. 403 at 9 (admitting that Dr. Davies' test "has not been described in the literature"). Dr. Davies was unable to identify a single literature reference where a forced degradation study was used to evaluate whether a compound was an antioxidant. Tr. 174:14-175:3; DTX 105; 97:16-21 (admitting that Alsante does "not explicitly" discuss a stress test to study the effect of potential antioxidants).

Third, Dr. Davies failed to quantify the known or potential rate of error in his experiment. There is no known rate of error because the experiment has never been conducted before, and Dr.

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[4] Par renewed its *Daubert* objection to Dr. Davies' study and related testimony at trial. Tr. 72:21-73:15; D.I. 272 at 2.

Davies made no attempt to reproduce his results. Because Dr. Davies' experiment is not supported by general acceptance in the community, the potential rate of error is significant. *See In re TMI Litig.*, 193 F.3d 613, 669 (3d Cir. 1999), *amended*, 199 F.3d 158 (3d Cir. 2000). Dr. Davies' study design was flawed. Dr. Davies did not model conditions of a transdermal patch. Tr. 355:8-368:11 (Michniak). Dr. Davies used T-butyl hydroperoxide, TBHP, as the oxidizing agent, rather than oxygen, which affected the oxidation process because TBHP can directly react with amines such as rivastigmine and aldehydes such as acetaldehyde. Tr. 243:21-245:16 (Ganem). This was improper also because Par's ANDA products are substantially free of peroxides. Tr. 368:12-371:20 (Michniak); JTX 53, JTX 74. Dr. Davies also used a very large excess of TBHP such that direct reaction with TBHP was the dominant process in the experiment, and that "oxidation by air would play a minimal role, if any" in his experiments. Tr. 245:17-246:24 (Ganem). Therefore, Dr. Davies' experiment is not an appropriate model for oxidative degradation in the presence of air, as specified in the '031 patent. *Id*; JTX 001 at 4:20-30. He did not even control for oxygen in his experiment. Tr. 197:21-198:14.

Dr. Davies also failed to account for numerous other components that are produced in his reaction, particularly, those that might be generated by side reactions with TBHP. Tr. 248:3-250:7, 253:5-254:23 (Ganem). Dr. Davies failed to account for about 20% of the non-volatile analytes, thereby distorting the actual percentages of the degradation by-products Impurity 4 and ECAV that Dr. Davies did measure. Tr. 253:5-254:10. Dr. Ganem testified that an experiment that fails to account for other components in the system would not be acceptable for publication in a peer-reviewed journal. Tr. 254:11-23. Dr. Davies also failed to account for the possibility of co-elution of these other components in the HPLC. Tr. 254:24-257:17 (Ganem). And Dr. Davies improperly normalized data to obscure errors in his experiments. Tr. 257:18-261:19

(Ganem); 198:15-199:24. Dr. Davies never even measured whether there was any acetaldehyde present in his vials. Tr. 197:6-20. Given the potential rate of error, no "scientifically valid conclusions could be drawn" from Dr. Davies' study. Tr. 261:20-262:4 (Ganem).

Fourth, Dr. Davies did not maintain necessary standards in his study. Tr. 196:24-197:5 (admitting that he did not see if his test would demonstrate an antioxidant effect for known antioxidant compounds). Plaintiffs assert that Dr. Davies utilized "proper controls" by comparing the acetaldehyde samples with the no-acetaldehyde samples, and that additional controls using known antioxidants were not needed because "it was already established that antioxidants reduce oxidative degradation." D.I. 403 at 9-10. But that misses the point entirely. Dr. Davies failed to show that his experiment can reliably tell the difference between compounds that are and are not antioxidants:

> [F]or a test of an antioxidant to be a scientifically valid method, the test should first of all show that known antioxidants display the expected antioxidant behavior that's been reported for them, and likewise, compounds that are known not to have any antioxidant activity should be shown in the Davies test likewise to exhibit no such activity. And absent those controls, those validations, I don't think one can draw any conclusions from an experiment.

Tr. 247:12-248:2 (Ganem). By failing to include proper standards, Dr. Davies' experiment was biased in favor of finding an antioxidant effect. Tr. 380:1-383:4 (Michniak). Indeed, another court excluded a test Dr. Davies conducted in part because Dr. Davies provided "nebulous standards for controlling the operation of his humidity test." *Warner Chilcott*, 2012 WL 1551709, at *25; *see also In re OxyContin Antitrust Litig.*, No. 04-md-1603, 2014 WL 128013, at *57 (S.D.N.Y. Jan. 14, 2014) (assigning Dr. Davies' testing protocol "no weight" because it failed to provide any reference to what an ordinary skilled artisan would do, and the court instead credited the opposing expert's test, which had a control to "standardize his results").

Fifth, Dr. Davies' methodology is not generally accepted in the scientific community to

evaluate antioxidant behavior, and has no relationship to established, reliable techniques. Tr. 247:1-11 (Ganem) ("Dr. Davies's experiment doesn't use any method I have ever encountered, any valid scientific method that I know of to test for the antioxidant capabilities of a chemical compound."); 470:12-19 (Buckton). Forced degradation studies are used to produce large amounts of degradants to develop analytical procedures and identify degradants that are being produced. Tr. 467:15-470:11 (Buckton); 412:4-414:6 (Michniak); DTX 591 at 12-13. Forced degradation studies are different from accelerated stability tests. Tr. 472:1-474:10 (Buckton).

Plaintiffs assert that two literature references describe the "use of stress tests to conduct excipient compatibility studies, which includes studying the effect of an antioxidant on a drug" and to "select[] suitable excipients." D.I. 403 at 11 (citing JTX 75, JTX 221). But as Dr. Buckton explained, the references do not describe or support the use of an antioxidant in a forced degradation study (Tr. 475:22-477:10), and excipient compatibility studies are not used to assess whether a compound is an antioxidant. Tr. 477:11-480:5. Therefore, the fact that forced degradation studies may be used in other, unrelated contexts does not save Dr. Davies' experiment. *Warner Chilcott*, 2012 WL 1551709, at *25 ("the fact that another scientist exposed pharmaceutical ingredients to humidity to explore completely unrelated properties does not save Dr. Davies's application of his humidity treatment in this case"); *see also Reliance Ins. Co. v. Keystone Shipping Co.*, 102 F. Supp. 2d 181, 190 (S.D.N.Y. 2000) (rejecting "unorthodox and unproven" application of standard technique), *aff'd*, 7 F. App'x 111 (2d Cir. 2001).

In addition to being unreliable, Dr. Davies' experiment does not "fit" or support his conclusions. *See Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 591 (1993). As stated above, forced degradation studies such as Dr. Davies' experiment are not used to assess antioxidant behavior. Dr. Davies' experiment is not a scientifically valid method for concluding

that acetaldehyde is an antioxidant. Nor is it predictive of what will happen in any pharmaceutical composition. Tr. 480:9-16 (Buckton); 382:16-22 (Michniak). Therefore, Dr. Davies' experiment is not evidence that Par's ANDA product contains an antioxidant that would infringe Claim 7. *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 743 (3d Cir. 1994) ("even if an expert's proposed testimony constitutes scientific knowledge, his or her testimony will be excluded if it is not scientific knowledge *for purposes of the case*"). In sum, the evidence at trial suggests that "Dr. Davies created the test purely for this case," and that "the proponents of the expert testimony are the only ones who vouch for its reliability." *Warner Chilcott*, 2012 WL 1551709, at *26. Dr. Davies' experiment should therefore be excluded.

b. Dr. Davies' Experiment Does Not Show Any Statistically Significant Antioxidant Effect of Acetaldehyde

Further, Dr. Davies' experiment shows no statistically significant results. Dr. Davies improperly conducted his statistical analysis using a one-sided T-test. Tr. 371:21-375:21, 351:17-354:17 (Michniak); DTX 540 at 171 ("[o]ne-sided tests are rarely appropriate"). When a proper two-sided T-test is used, Dr. Davies' data points were not statistically significant (p-values > 0.05). Tr. 375:22-377:7 (Michniak).[5] Using the standard approach in the scientific community, a reliable conclusion cannot be drawn from Dr. Davies' data. Tr. 377:8-15 (Michniak). Dr. Davies' after-the-fact attempts to re-do his statistical analysis by using a linear regression model also do not demonstrate statistical significance. Tr. 377:20-379:24 (Michniak)

[5] Plaintiffs improperly assert that, even under Dr. Michniak's statistical analysis, a confidence interval of at least 87% is "far above the preponderance threshold needed to show infringement." D.I. 403 at 7. But confidence intervals do not address the question of whether a patentee has met the preponderance of the evidence standard. *See Pfizer Inc. v. Teva Pharm. U.S.A., Inc.*, 882 F. Supp. 2d 643, 714 (D. Del. 2012), *aff'd*, --- F. App'x ----, 2014 WL 463757 (Fed. Cir. Feb. 6, 2014). For example, a confidence interval of 51% would be overwhelmingly interpreted by the scientific community as showing no evidence of a difference, not as evidence of a probable difference. *See* Tr. 411:1-412:3 (Michniak).

("What he did is go back and do all of these other tests and basically massage the data. Because you're really not allowed to do statistics after you've got the data because it introduces bias... That's an absolute no-no.")

E. Plaintiffs Failed to Show that Par's ANDA Products Will Likely Contain "About 0.01 to About 0.5 Percent by Weight of an Antioxidant"

Plaintiffs rely entirely on Par's ANDA specification—which allows up to 1000 ppm (0.1%) acetaldehyde in the rollstock from which the product is made—to assert that Par's ANDA product meets the limitation "about 0.01 to about 0.5 percent by weight of an antioxidant." D.I. 403 at 23-24. Plaintiffs provided no opinions or other evidence that Par's ANDA product would, if approved, likely contain about 0.01 to about 0.5 percent by weight of acetaldehyde, even if acetaldehyde were found to be an antioxidant. But cases have permitted a patentee in an ANDA case to rely solely on the ANDA specification only when the ANDA ***directly*** addresses the issue of infringement in the first instance. *Alcon*, 745 F.3d at 1186. Par's ANDA fails to meet this requirement. Claim 7 requires an amount "of an ***antioxidant***." Par's ANDA includes no specification for an amount of antioxidant. Tr. at 462:2-12 (Buckton).

Rather, Par's ANDA says that it does not contain an antioxidant. DTX 595 at 232-233; Tr. 436:1-3 (Buckton). And it is undisputed that nothing in the ANDA product is functioning as an antioxidant. *Id.* Acetaldehyde, according to the specification, is a residual solvent/manufacturing impurity, and serves no purpose in the formulation. Tr. 459:22-462:1 (Buckton). Nor does the ANDA, the '031 patent, or any pharmaceutical literature state that acetaldehyde is an antioxidant. Plaintiffs had to rely on Dr. Davies' experiment, not performed on Par's ANDA product, for their allegation that acetaldehyde is an antioxidant. By Plaintiffs' own actions and admissions, Par's ANDA specification does not define a compound "such that it meets the limitations of an asserted claim." *Sunovion*, 731 F.3d at 1280.

Because Plaintiffs have chosen to go beyond the ANDA specification to try to show infringement, ***all*** pertinent evidence—including the measured levels of acetaldehyde and stability data on ANDA batches that were manufactured—must be considered. *Alcon*, 745 F.3d at 1186; *Glaxo*, 110 F.3d at 1570. Plaintiffs chose not to put forward an infringement case under this controlling standard, and judgment should therefore be entered in Par's favor. Further, batches of Par's ANDA product all had measured levels of acetaldehyde outside of the claimed range (DTX 585B), and Plaintiffs did not assert that these measured levels in batches of Par's ANDA product meet the claimed range.

1. If the ANDA Itself Does Not Resolve the Question of Infringement in the First Instance, All the Relevant Evidence Must be Considered

Because drug manufacturers are "bound by strict statutory provisions to sell only those products that comport with the ANDA's description of the drug," the ANDA specification may control the infringement inquiry. *Alcon*, 745 F.3d at 1186. For the ANDA specification to control, however, it must define a proposed generic drug "in a manner that ***directly*** addresses the issue of infringement." *Id.* (emphasis added). Indeed, "there may well be genuine disputes as to whether the ANDA specification defines the compound with sufficient particularity to answer the infringement inquiry." *Abbott Labs. v. TorPharm, Inc.*, 300 F.3d 1367, 1373 (Fed. Cir. 2002) (citing *Glaxo*, 110 F.3d at 1569-70). If the ANDA specification does not sufficiently define a proposed generic drug in the context of the infringement issue, then other evidence should be considered. *See, e.g.*, *Sunovion*, 731 F.3d at 1279; *Glaxo*, 110 F.3d at 1569-70. Therefore, the inquiry follows a two-step process. The first step is whether the ANDA specification defines a compound such that it meets the claim limitation. *Sunovion*, 731 F.3d at 1280. If not, evidence beyond the specification, such as actual samples and test results, must be considered. *Glaxo*, 110 F.3d at 1569.

In *Sunovion*, the ANDA specification directly addressed the issue of infringement. The issue was whether Reddy's proposed generic drug contained less than 0.25% of the levorotary isomer of eszopiclone. 731 F.3d at 1274. Reddy initially submitted an ANDA specification for 0.3-1.0% of the levorotary isomer, which fell outside the claimed range. However, FDA stated that the proposed limit was not acceptable, and required Reddy to tighten it to NMT (not more than) 0.30% (0.0-0.3%). *Id.* at 1274-75. In response, Reddy amended its ANDA specification to NMT 0.6% (0.0-0.6%) of the claimed isomer. *Id.* at 1275. Reddy then submitted a declaration to the district court—but not to FDA—that it would market only generic eszopiclone tablets containing 0.3-0.6% of the claimed isomer, notwithstanding that it had not gained FDA approval for that level of impurity. *Id.* at 1275. Notably, FDA expressly rejected the isomer range in Reddy's declaration to the district court (0.3-0.6%) and required Reddy to amend its ANDA specification to isomer concentrations below that range. The Federal Circuit held that Reddy's amended ANDA specification infringed the patent. *Id.* at 1280.

The Federal Circuit stated three reasons for its conclusion that the ANDA specification controlled the infringement inquiry. First, Reddy's ANDA specification "clearly describes a product that meets the limitations of the asserted claims." *Id.* at 1280. The court noted that FDA had already rejected Reddy's attempt to specify 0.3-1.0% of the isomer, in favor of 0.0-0.3%, which encompassed the infringing range. *See id.* at 1274-75. Second, the Federal Circuit stated that Reddy's focus on its "so-called certification to the district court—pledging to follow internal manufacturing guidelines that may produce a drug composition ***for which the FDA has indicated it will not grant approval***—as 'other evidence' dispositive of the infringement inquiry is misplaced." *Id.* at 1279. Third, the facts were "significantly different" from *Bayer AG v. Elan Pharmaceutical Research Corp.*, 212 F.3d 1241 (Fed. Cir. 2000) and *Glaxo*, where the ANDA

specification was held insufficient to find infringement. 731 F.3d at 1279. The court stated that in contrast, in *Glaxo*, "we endorsed the district court's reference to evidence including biobatch data and actual samples of the generic composition, which Novopharm had submitted to the FDA, as relevant to the infringement inquiry because ***the ANDA specification itself did not resolve the question of infringement in the first instance***." *Id.* at 1279-80.

The issue in *Glaxo* was whether the proposed generic drug product infringed claims requiring Form 2 of a compound. The ANDA specified that the product would be approximately 90% pure Form 1 (with impurities that could include Form 2). The court did not permit Glaxo to merely show that the identity of the remaining 10% could be Form 2, and then rely on the 90% specification as permitting up to 10% Form 2. Rather, the court squarely rejected the position Plaintiffs assert here: that the district court should have focused "solely on the fact that the scope of approval sought by Novopharm would allow it to manufacture compositions containing Form 2." *Glaxo*, 110 F.3d at 1567. Instead, the court held that "the statute requires an infringement inquiry focused on what is likely to be sold following FDA approval. This inquiry must be based on all of the relevant evidence, including the ANDA." *Id.* at 1568.

Plaintiffs seized on language in *Sunovion* that "[i]f it had no intent to infringe, Reddy should not have requested, or should not accept, approval to market a product within the scope of the claim." D.I. 403 at 24. But that language makes sense (and can be reconciled with *Glaxo*) only if the ANDA specification unambiguously defines the same compound specified in the patent claim. Indeed, "NMT 1000 ppm" is a fairly standard specification limit and applies to other impurities in Par's ANDA as well. Given that Plaintiffs themselves could not identify any antioxidant in the ANDA product based on the ANDA alone (DTX 568 at 11), the "intent" language in *Sunovion* has no relevance to this case. Par had no notice what Plaintiffs might

contend to be an antioxidant, and no reason to undertake the necessary analytical work to support a narrower specification for a compound not known to be an antioxidant.

2. Par's ANDA Specification Does Not Resolve the Issue of Infringement in the First Instance

The infringement issue in this case is whether Par's ANDA Products contain "about 0.01 to about 0.5% by weight of an antioxidant." Plaintiffs assert a mix-and-match approach, whereby they may elect to assert evidence outside the ANDA to try to prove that acetaldehyde is an antioxidant, but then may turn a blind eye to the "actual samples and the extensive technical data required by the FDA" (*see Glaxo*, 110 F.3d at 1569 n.2) when determining the amount of acetaldehyde in the ANDA product. No Federal Circuit case Par has been able to locate has applied such a piecemeal analysis. Cases have either relied solely on the ANDA, or have considered all of the relevant evidence to conclude what likely will be sold.

Plaintiffs assert that Par's reliance on *Glaxo* is misplaced, because the "present dispute, just as in *Sunovion*, simply requires a comparison of the numerical ranges in claim 7 of the '031 Patent and Par's ANDA specification." D.I. 403 at 24-25 ("Under *Sunovion*, a finding of infringement of the amount limitation must necessarily ensue"). Plaintiffs are incorrect. First, there is no separate "amount limitation." The single limitation at issue specifies the amount of "antioxidant." Second, in *Sunovion*, the ANDA specification directly addressed the claim element—both the patent claim and the ANDA specification defined the identical levorotary isomer. 731 F.3d at 1274. No testing, expert opinion, or other evidence outside of Reddy's ANDA was necessary to prove that they were the same compound. Here, Par's ANDA contains no specification for an amount of antioxidant, and only after Plaintiffs had conducted testing outside of the ANDA were Plaintiffs able to even assert that acetaldehyde was an antioxidant.

Further, in *Sunovion*, the court relied on the fact that FDA required Reddy to amend its

specification to include an amount of the levorotatory isomer that was nearly identical to the claimed range (0.0-0.3%), and would not approve the amount that Reddy certified that it would manufacture (0.3-0.6%). *Id.* at 1279. Here, acetaldehyde is not required to be present at all. FDA has made no indication that Par's ANDA would be approvable only if it contained amounts of acetaldehyde corresponding to the claimed percentages. Indeed, such a requirement would make sense only if FDA and Par believed acetaldehyde to have a function (i.e. antioxidant). Accordingly, *Sunovion* cannot be extended to numerical ranges that the ANDA does not directly link to the same compound or function as defined in the claim.

Finally, *Sunovion* does not apply because that court specifically stated that its holding was "that any so-called certification pledging not to infringe cannot override" the ANDA specification. 731 F.3d at 1280. This case involves no such "so-called certification," but instead ***nine batches*** of Par's ANDA products that all have either no detectable acetaldehyde levels, or minimal acetaldehyde levels that are more than 70% below the lower end of the claimed range for an antioxidant. These facts place the present case squarely within the holding of *Glaxo*, and outside of *Sunovion*.

3. Par's ANDA Products Do Not Likely Contain "About 0.01 to About 0.5 Percent" of Acetaldehyde

Plaintiffs provided no evidence (nor did they even assert) that Par's ANDA product, if approved, would likely contain "about 0.01 to about 0.5 percent by weight" of acetaldehyde. Tr. 462:13-465:1 (Buckton). Moreover, Par provided compelling evidence that the ANDA product, if approved, would have acetaldehyde concentrations far below the claimed range, if it were present at all. The measured values ranged from none detectable to a single instance of 30 ppm; the highest mean value measured was 25 ppm (0.0025%). Tr. 464:4-465:1 (Buckton); DTX 585B. All measured amounts fell below the claimed range of "about 0.01 to about 0.5 percent by

weight of an antioxidant."

Moreover, the highest measured amounts of acetaldehyde were 25% of the low end of the range, and thus not numerically "about" the same as the claimed range. *Id.* The measured acetaldehyde also is not "about" 0.01% because it does not function to stabilize rivastigmine in the composition. *See Cohesive Techs., Inc. v. Waters Corp.*, 543 F.3d 1351, 1368 (Fed. Cir. 2008). During prosecution of the '031 patent, the examiner rejected the claims, stating that the specification did not enable the use of ***any*** amount of antioxidant in the composition to achieve the stabilization of compound A. The applicants overcame the rejection by adding the range limitation "about 0.01 to about 0.5 percent by weight" of the antioxidant. Tr. 423:6-430:1 (Buckton); DTX 249 at N1075, N1078. Therefore, to fall within the "about" limitation, the purported antioxidant must function in the composition to achieve the stabilization of rivastigmine. *Id.* Par's stability data indicate that the acetaldehyde in Par's ANDA products does not function to stabilize rivastigmine. Tr. 465:5-467:2 (Buckton).

III. CONCLUSION

For the reasons set forth herein and based on the evidence presented at trial, Par does not infringe Claim 7 of the '031 patent.

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CERTIFICATE OF SERVICE

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